

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:3730
ANSWERED ON:12.12.2001
MANUFACTURING OF BANNED DRUGS
RAMESH CHAND TOMAR

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether attention of the Government has been drawn to the news-item captioned 'Banned in U.S. available here' appearing in 'The Times of India' dated August 26, 2001;
- (b) if so, whether several drugs which are banned in the United States and other developed countries are freely manufactured and available in the country;
- (c) if so, the facts thereof; and
- (d) the corrective steps contemplated in this regard?

Answer

MINISTER OF HEALTH AND FAMILY WELFARE (DR. C.P. THAKUR)

(a) Yes, Sir.

(b) to (d) Certain drugs and formulations withdrawn in some countries at times, continue to be marketed in other countries because the decision to do so is based on risk assessment process which is influenced by a number of factors such as the disease pattern in a country, the varying reactions of certain ethnic groups in a given population to the drug, availability of safer substitutes as well as the cost factor involved in the treatment of a particular disease etc. The drugs marketed in the country are examined through an Expert Committee on a continuous basis to weed out harmful/irrational drugs.

Two Drugs, namely Cisapride and Phenylpropylamine were withdrawn in USA in July, 2000 & November, 2000 respectively. However, these drugs are also available in countries like Sweden, Australia etc. with restricted indications. In India also the status of these drugs have been examined by an Expert Committee and as per the recommendations, the marketing of these drugs have been allowed for specific indications.

Recently, one cholesterol reducing drug 'Cerivastatin' has been withdrawn in USA due to adverse reports of fatal rhabdomyolysis associated with this drug. In India, M/s. Bayer India Ltd., and M/s Torrent Ahmedabad who were permitted to market Cerivastatin have also withdrawn it from the market. All State Drug Control Authorities have been directed to ensure that Cerivastatin tablets are not marketed anywhere in the country.